
Global Interdependence and the Private Sector

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Richard Sawyer in the preceding paper made two points of particular relevance to my comments. First he stated, in agreement with a broad spectrum of observers, that biotechnology provides perhaps our best opportunity for maintaining and increasing agricultural yields into the 21st century. Second, he notes that public support for agricultural research is in decline, in places in steep decline, at virtually all levels from bilateral to local. Perhaps the hardest hit are the Consultative Group for Agricultural Research (CGIAR) centers with funding down about 35 percent over the past three years. In the U.S. we are relatively fortunate to have had our reductions in Federal funds largely limited to the controlled but relentless force of inflation; nominal allocations have held constant while the real value sinks.

Clearly, something must be equating the promise with the reality, and that something is the private sector. This obvious deduction is readily supportable by the available data. Although figures vary, estimates are that the private sector provides three quarters of the funding for agricultural biotechnology, or roughly U.S. \$900 million worldwide in 1985 (James 1991; Persley 1990). Nor is this research cheap. Private estimates are that over U.S. \$20 million are needed for a single application of a transgenic crop (quoted in Altman 1994). A portion of that cost is regulatory approval with expenditures in the U.S. verging on U.S. \$2 million per application. Other countries, including developing countries, need not consider that cost except to the degree they require or demand U.S. approval prior to consideration for national use.

Clearly, the private sector will require a return on this significant investment. About that there is nothing new. What is new is the self-reproducible nature of much of the technology, meaning that intellectual property rights protection (IPR) in the form of patents and Plant Breeders' Rights (PBR) is an essential component in capturing a return. Second, the commercial life of many of these products may be short. They are commercially vulnerable to the breakdown of resistance in some cases and, for all, competition from new and improved products. A response to limited, temporal markets is the expansion of geographical markets. Taken together these mean that technology access for developing countries is going through a revolution of its own. More technology

is becoming available and overseas markets are being avidly sought. At the same time, much will be available only on a commercial basis and then only when the internal systems, notably IPR legislation, are satisfactory to the technology suppliers.

Such a scenario describes technological dependence, not interdependence. However, that ignores the key input into genetic engineering—the genetic resources. Genetic resources, as has been well established, originate predominately from developing countries. Those resources until recently have been treated as the common heritage of humankind as was formally recognized in the Food and Agriculture Organization (FAO) publication *Undertaking for Plant Genetic Resources*. The Convention on Biological Diversity forever altered that presumption by declaring genetic materials to be the sovereign right of the government where they occur to exploit (Article 3). That is interdependence.

Countries have been utilizing that option, the best publicized being the agreement between Merck Research Laboratories in Rahway, New Jersey, USA and the Instituto Nacional de Biodiversidad in Costa Rica, Central America (Merck/INBio), but there are others (Reid et al. 1993). Those agreements however are based on a contractual arrangement among the parties. Contracts are an effective mechanism for such agreements (see Simpson and Sedgo 1992), but are limited by placing no obligations on third parties. Anyone but the signatories who acquire a product legally, such as purchasing a transgenic potato in a local market, may treat it as being public property. Contracts fundamentally work from secrecy, and secrecy is neither generally possible nor really appropriate for agriculture (see Lesser 1994).

What then appears to be the situation is the interdependent parties are willing to pay each other, but lack a mechanism. The juxtaposition in the Biodiversity Convention of the articles treating the commercialization of genetic resources (Article 15) and the acquisition of technologies (particularly biotechnologies) (Article 16) could suggest a barter arrangement using the two. Barter implies a direct exchange of equal value without the use of money. However, barter is an extremely complex exchange arrangement, especially as regards enforcement of the conditions. The appropriate mechanism is intellectual property rights, but my position is that they are at present inadequate in most developing countries for acquiring biotechnologies and essentially nonexistent everywhere for claiming remuneration for genetic materials.

OBJECTIVE

What exists then in my view is a global interdependence lacking a facilitating mechanism. A portion of this, and that portion to be addressed here, is the apparent position by many developing countries that IPR on balance do not serve national interests, nor do they provide equity in either its moral or prac-

tical sense. The purpose of this paper is to set forth in outline my assessment of what is needed to structure an international system of rights which recognizes and responds to this interdependence. That assessment will by necessity consider both developed to developing, and developing to developed, country exchanges, referred to here as North-South (N-S) and South-North (S-N) exchanges. We begin with N-S transfers.

My institution, ISAAA, the International Service for the Acquisition of Agri-biotech Applications, facilitates such transfers and is the source of several examples; ABSP (Agricultural Biotechnology for Sustainable Productivity) among other groups could provide additional examples. The examples are the transfer of virus resistance (PVX and PVT) using a Monsanto technology into Mexican potato varieties, and the transfer of papaya ringspot virus resistance, a Cornell University technology, to several countries including Brazil and Thailand.

NORTH-SOUTH TECHNOLOGY TRANSFER

Geographical Scope of IPR Protection

Intellectual Property Rights (IPR) protection is national, meaning that it applies only in those countries where protection is held. As of 1990, 63 countries explicitly excluded patents for plants, about half of which are developing countries (WIPO 1990). The situation for animals is slightly more restrictive. The ban on plants is not as complete in all these countries as might appear to be the case because the prohibition reads to "plant varieties," not plants per se. This has allowed the European Union (EU) to state the option of defining "variety" narrowly and to grant patents for plants not in a "fixed form" (see Crespi 1992). Potentially, any other countries using similar exclusionary language could act similarly. At minimum the protection situation is complicated.

Plant Breeders' Rights (PBR) legislation is similarly limited in geographic scope with only 23 countries and but one developing country (South Africa) signatory in April 1993 to the International Union for the Protection of New Varieties of Plants (UPOV), the international convention. Several countries have national laws—including Argentina, Chile and Zimbabwe—but the particulars are difficult to come by. Thus, presently, the geographic scope of IPR as applicable to biotechnology applications in living organisms is very limited.

Some of this will change under the recently adopted text of the Uruguay Round of the General Agreements on Tariffs and Trade (GATT) which over one hundred countries, some 70 of which are developing countries, have signed. One aspect of the agreement, known as Trade-Related Aspects of Intellectual Property Rights (TRIPs) requires all countries within a five to ten-year period to provide the following forms of protection (MTN/FA II-A1C):

- Contracting parties shall provide for the protection of plant varieties by patents and/or an effective *situ generous* (meaning separate law like UPOV) system (Section 5, Article 27[3b]).

- Plants and animals other than microorganisms and “essentially biological processes for the production of plants and animals” may be excluded from protection (Section 5, Article 27 [3b]).

- Patents maybe prohibited to protect *order public* or morality, provided there is a justification exceeding the mere prohibition in domestic law (Section 5, Article 27[2]).

Other stipulations exist, but lie further outside our scope. In my judgment, these requirements even when fully implemented will leave gaps in coverage which might be of significance for agricultural biotechnology applications. It is quite evident that countries may exclude plants and animals from patent protection by choice. Even the terminological issues discussed above regarding the exclusions in the EU would seem not to apply. In the EU, as noted above, the legislation refers to varieties whereas under TRIPs, reference is made to plants and animals. The public morality provision is a further delimiter if desired. Countries can be expected to adopt PBR; indeed India is presently in the process. However, PBR does not protect an engineered gene which can be transferred to another variety by backcrossing. Thus PBR alone may be considered by some owners of genetic technologies as being insufficient. More encompassing laws, however, will come only when countries, and in particular developing countries, consider it in their advantage to pass such laws.

ROLES OF IPR IN DEVELOPING COUNTRIES

The principal justification of IPR is as an incentive for private investment (e.g., Machlup 1958). Evidence of its effects, while by no means complete, is generally supportive of that expectation for the industrialized countries. For the developing countries the issue is somewhat different, as legitimate questions have been raised about their competitive position as producers of world class technologies. I personally believe that matter can be answered in the positive (see literature review in Lesser 1991, Chap. 4), but the issue to be addressed here is not production but access. What role does IPR play in the willingness of private firms to make available easily copied technologies like plants?

About that we have little specific evidence primarily because the subject is only now arising with potentially very valuable agricultural biotechnologies nearing the commercialization stage. Moreover it is not clear that the major proprietary suppliers have a clear policy, probably because there are larger markets to be considered first. Offers have, I understand, been made (e.g., to India) to give blanket rights for an upfront fee described as ten cents on the dollar. Yet few countries are willing or financially able to enter such a deal. Among its unattractive aspects is the shifting of product performance risk to the user.

Similarly, many countries are hesitant to allow protection, which implies the payment of royalties for what can in all probability be acquired free once

marketed. Presumably a similar recognition led the investor to offer (unsuccessfully) blanket rights at a large discount. Yet acquisition in that manner, even when legal, involves a time cost. Backcrossing *Bacillus thurengiensis* (Bt) genes into a locally adapted cotton variety takes about four years, four more years of heavy pesticide applications, followed by the biosafety review. And then the seeds must be propagated for wide use. What should developing countries be doing? ISAAA, which must eventually assist in identifying a response, has no real answer.

There is another class of IPR issues which poses even less clear issues. It can be typified by the DuPont Corporation, Wilmington, DE, USA "gene gun" case. Where the gene gun is patented, I understand, DuPont (operating through its licensee Agracetus Inc., Middleton, Wisconsin, USA) requires rights to resultant products as a condition for a license. Where the gene gun is not patented (e.g., in Brazil) it is said to be manufactured at a significant level which is perfectly legal. But what are the possible costs to Brazil? Is there a moral obligation? Can it legitimately be argued that there is no moral obligation to private companies or to "rich" multinationals? Can the products be imported into countries (like members of the European Patent Union) where direct and indirect products of patented technologies cannot be sold without permission? Probably not. What will happen if in the future Brazilian scientists seek other technologies directly from DuPont or from other private firms? Will/can DuPont hold a commercial grudge? Should this concern Brazil? How will the World Bank and other bi/multilateral donors respond, as much project funding will, directly or indirectly, be coming from those sources?

Possible Action

In order to meet their GATT/TRIPs commitments, some 70 developing countries will over the coming several years be modifying their IPR systems substantially. Concurrently, many new agricultural biotechnology applications are expected to become available. This is the proper time to consider the appropriate forms of those laws. The format can be similar to the assistance which ISAAA, ABSP, SEI (Stockholm Environment Institute, Sweden), the Dutch Government and other groups have provided for biosafety regulations.

To me what is lacking is a clear concept of the program content. This is primarily because the ultimate issue is between countries and the private sector, and secondarily between countries and university licensing groups. Thus I am calling on private interests to develop positions and share those positions with developing countries. Clearly the private sector has expectations of what developing countries should do; those expectations must be both clear and realistic. Many in the public sector, including ISAAA, can help with the delivery of those positions, but we cannot generate them. At the same time it is appropriate to begin thinking about ways to simplify access to materials. Present trends suggest a not-distant future when any technology may have multiple claimants making the process of identifying the owners and negotiating with

them onerous. Consider the papaya ring spot virus technology ISAAA is brokering. Aspects are potentially claimable by Upjohn Company in Kalamazoo, Michigan, USA, Cornell University and DuPont, and this is only the beginning. True, this already occurs for other technologies, but those technologies are generally not directed to multiple users in scores of countries. Some kind of simplification, possibly including a clearinghouse agency or predated royalty rate structure for many of the more minor innovations, is needed.

SOUTH-NORTH TRANSFERS

As noted, this form of exchange is presumed to include the utilization of genetic materials for agricultural developments and other uses. For simplicity, materials currently held *ex situ* will not be discussed because their legal status is unclear; the Biodiversity Convention (Article 15 [c] [3]) makes special note of its applicability to materials acquired before it went into effect in December 1993.

In an earlier effort I attempted to characterize the limited protection for genetic materials under existing laws (Lesser 1994). That evaluation covered not only patents and Plant Breeders' Rights, but also possible extensions through Codes of Conduct and (proposed but not enacted) folklore rights. All were found lacking in providing meaningful protection, protection leading to possible collection of royalties. The principal confounding issue is the identification of just what is being protected. An absence of a clear delineation creates broad ambiguity over who is claiming what. That in turn interferes with research access and creates the likelihood of conflict among countries (presuming they are the titleholders) with identical or similar protected materials. Technical solutions have been proposed, but they are costly for materials—the bulk of which will have little commercial value.

The current course of legal activity is along the lines of access laws. Many countries have these for pharmaceutical purposes while others (e.g., Queensland, Australia and, I believe, Brazil) are adopting them for all product access. Some legal stipulation is required if countries are to prevent someone from simply carrying off materials as in most cases they presently have full legal rights to do. Access laws are a means of implementing the "sovereign rights" to genetic materials specified under the Biodiversity Convention (Article 3). Indeed, modes and modalities for legislation will be discussed at the first Meeting of the Parties of the Biodiversity Convention in late 1994.

For me, the discussion of particular text is premature because objectives remain unclarified. They are often proposed in terms of equity, but equity has many aspects. One form is equity for past contributions, the multigenerational selection needed in the creation of a landrace, for example. Another form involves payments for future contributions, whether for research and development leading to new useful products or for conservation activities. Either or both to some degree are possible and justifiable, but the matter must be dis-

cussed forthrightly, or at least identified. For myself, I see the additional benefits to humanity of payments for future contributions.

A second major question is the functioning of the laws. Major IPR laws operate through exclusion, the right to refuse access. Indeed, that is really the only benefit they provide. Some countries, however, allow so-called licenses-of-right, blanket compulsory licenses for everyone meeting the requirements, (e.g., the payment of a royalty). Compulsory licenses remain an anathema to many supporters of IPR, but to me they are the only reasonable solution for the mass of materials likely to be protected under these new systems. Licenses of right emphasize access which is critical for agricultural applications. At the same time a streamlined system will be less costly to operate, returning more to the owners by absorbing less in transactions costs.

Possible Actions

Steps are being taken for the preparation and subsequent adoption of legislation controlling access to genetic resources. While those laws might be justified largely by the understandable desire to collect payments from private firms, they will also affect access for research and other uses. For that reason it is critical that a broader group becomes knowledgeable about and involved in the process. A change of venue is also desirable. Presently, much will be conducted within the auspices of the Biodiversity Convention which, while appealing at one level, is not really appropriate with its 300+ delegates for the consideration of such a detailed topic.

CONCLUSIONS

With biotechnology now near to having numerous applications in developing countries, it is abundantly clear that little of that technology will be available without charge. Developing countries need those materials and must pay for what is used. At the same time, and in partial response, developing countries are seeking payment for their own genetic materials, these in the form of largely unimproved germplasm. In many regards, placing access on a cash basis facilitates the process, since at least what is being requested can be readily understood and negotiated.

However, we do not presently have a real market for these materials/technologies, a market which operates efficiently as do markets for major agricultural commodities. Inefficient markets absorb much of the value of the products exchanged, value which should go to the owners. Principal limitations, in my viewpoint, are: 1. the weakness/lack of Intellectual Property Rights in many recipient countries and 2. the virtual absence of laws controlling access to genetic materials. We are all dependent on the outcome of the process of rectifying those gaps; it is time that more of us become knowledgeable about and involved in the process of filling them.

REFERENCES

- Altman, D. W. 1994. Technology Transfer Initiatives of the International Service for the Acquisition of Agri-Biotech Applications. *AgBiotech News and Information*. 6(6):131N-134N.
- Crespi, R. S. 1992. Patents and Plant Variety Rights: Is There an Interface Problem? *Int. Rev. Industrial Property and Copyright Law*. 23:168-84.
- James, C. 1991. The Transfer of Proprietary Agricultural Biotechnology Applications From the Industrial Countries to the Developing Ones: The International Biotechnology Collaboration Program. In A. Brandolini, ed. *Revista de Agricultura Subtropicales e Tropicales*. Istituto Agronomico per L'Oltremare, Florence, Italy, pp. 5-24.
- Lesser, W. 1994. Institutional Mechanisms Supporting Trade in Genetic Materials: Issues Under the Biodiversity Convention and GATT/TRIPs. *UNEP Environment and Trade No. 4*. Nairobi, Africa.
- Lesser, W. 1991. *Equitable Patent Protection in the Developing World: Issues and Approaches*. Eubios Ethics Institute, Tsukuba, Japan.
- Machlup, F. 1958. *An Economic Review of the Patent System*. Study of the Subcommittee on Patents, Trademarks and Copyrights. Committee on the Judiciary, U.S. Senate. Study No. 15.
- Persley, G. J. 1990. Beyond Mendel's Garden: Biotechnology in the Service of World Agriculture. *Biotechnology in Agriculture No. 1*. CAB International, Oxford, England.
- Reid, W.V., S.A. Laird, C.A. Meyer, R. Gamez, A. Sittenfeld, D.H. Janzen, M.A. Gollin and C. Juma, eds. 1993. *Biodiversity Prospecting: Using Genetic Resources for Sustainable Development*. World Resources Institute, Washington, DC, USA.
- Simpson, R. D. and R. A. Sedgo. 1992. Contracts for Transferring Rights to Indigenous Genetic Resources. *Resources*. 109:1-6.
- World Intellectual Property Organization (WIPO). 1990. *Exclusions from Patent Protection*. HL/CM/INF/I, Rev. Geneva, Switzerland.